



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
|-----------------|-------------|----------------------|---------------------|------------------|

10/814,620

03/31/2004

Arthur O. Tzianabos

B0801.70280US01

5444

7590 12/21/2006
Alan W. Steele, M.D., Ph.D.
Wolf, Greenfield & Sacks, P.C.
600 Atlantic Avenue
Boston, MA 02210

EXAMINER

ROONEY, NORA MAUREEN

ART UNIT

PAPER NUMBER

1644

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE |
|--|-----------|---------------|
|--|-----------|---------------|

31 DAYS

12/21/2006

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/814,620

Applicant(s)

TZIANABOS ET AL.

Examiner

Nora M. Rooney

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 July 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19,23,37,41,46,57,60,67,72,73 and 93 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-19,23,37,41,46,57,60,67,72,73 and 93 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. § 121:
 - I. Claims 1-6, 7 and 17-18, drawn to a method for treating an allergic condition other than asthma in a subject comprising administering PSA1 and an anti-allergy medicament, classified in Class 424, subclasses 282.1 and 234.1.
 - II. Claims 1-6, 8 and 17-18, drawn to a method for treating an allergic condition other than asthma in a subject comprising administering PSA2 and an anti-allergy medicament; classified in Class 424, subclasses 282.1 and 234.1.
 - III. Claims 1-6, 9 and 17-18, drawn to a method for treating an allergic condition other than asthma in a subject comprising administering PSB and an anti-allergy medicament; classified in classified in Class 424, subclasses 282.1 and 234.1.
 - IV. Claims 1-6, 10 and 17-18, drawn to a method for treating an allergic condition other than asthma in a subject comprising administering Streptococcus pneumoniae capsular polysaccharide 1 (CP1) and an anti-allergy medicament; classified in classified in Class 424, subclasses 282.1 and 234.1.
 - V. Claims 1-6, 11 and 17-18, drawn to a method for treating an allergic condition other than asthma in a subject comprising administering de-N-acetylated Salmonella typhi Vi antigen and an anti-allergy medicament; classified in Class 424, subclasses 282.1 and 234.1.

Art Unit: 1644

VI. Claims 1-5, 12 and 17-18, drawn to a method for treating an allergic condition other than asthma in a subject comprising administering aminated pectin and an anti-allergy medicament; classified in Class 514, subclass 23.

VII. Claims 1-5, 13 and 17-18, drawn to a method for treating an allergic condition other than asthma in a subject comprising administering synthetic peptidoglycan Compound 15 and an anti-allergy medicament, classified in Class 424, subclasses 280.1 and 279.1.

VIII. Claims 1-4, 14 and 17-18, drawn to a method for treating an allergic condition other than asthma in a subject comprising administering a peptide and an anti-allergy medicament, classified in Class 424, subclass 851.1 and Class 530, subclass 350.

IX. Claims 1-4, 15 and 17-18, drawn to a method for treating an allergic condition other than asthma in a subject comprising administering a polymer wherein the polymer is $(K-D)_n$ wherein n is an integer between 10 and 100 inclusive and an anti-allergy medicament; classified in Class 424, subclasses 280.1 and 78.08.

X. Claims 1-4, 16 and 17-18, drawn to a method for treating an allergic condition other than asthma in a subject comprising administering a polymer wherein the polymer is $(K-(Xaa)_m-D)_n$ wherein each Xaa is independently any neutral amino acid, m is an integer between 0 and 8, inclusive and n is an integer between 10 and 100 inclusive and an anti-allergy medicament; classified in Class 424, subclasses 280.1 and 78.08.

XI. Claim 19, drawn to a method for treating a subject having an allergic condition associated with an identified allergen comprising exposing the subject to the identified allergen and administering an isolated polymer including repeating units of a charge motif characteristic of B. Fragilis polysaccharide A (PSA), classified in Class 424, subclasses 282.1 and 234.1.

XII. Claim 23, drawn to method for treating asthma in a subject comprising administering an isolated polymer comprising repeating units of a charge motif characteristic of *B. fragilis* polysaccharide A (PSA); classified in Class 424, subclasses 282.1 and 234.1.

XIII. Claim 37, drawn to a method for treating a subject having asthma associated with an identified allergen comprising exposing the subject to the identified allergen and administering to the subject a polymer that includes repeating units of a charge motif characteristic of *B. fragilis* polysaccharide A (PSA); classified in Class 424, subclasses 282.1 and 234.1.

XIV. Claim 41, drawn to a method for inducing Il-10 production comprising isolating a T regulatory cell and contacting the cell with an isolated polymer that includes repeating units of a charge motif characteristic of *B. fragilis* polysaccharide A (PSA), classified in Class 424, subclasses 282.1 and 234.1.

XV. Claim 46, a method for inducing expression of inducible costimulatory molecule (ICOS) on a CD4⁺ cell comprising contacting a CD4⁺ cell with an effective amount of an isolated polymer to induce expression of ICOS on the CD4⁺ cell wherein the polymer comprises repeating units of charge motif characteristic of *B. fragilis* polysaccharide A (PSA) and measuring an increased ICOS expression on the CD4⁺ cell, classified in Class 424, subclasses 282.1 and 234.1.

XVI. Claims 57 and 60, drawn to a method for inducing proliferation of T regulatory cells comprising isolating population of T cells and contacting the population with an isolated polymer including repeating units of charge motif characteristic of *B. fragilis* polysaccharide A (PSA); classified in Class 530, subclass 387.3, and 391.1; classified in Class 424, subclasses 282.1 and 234.1.

XVII. Claim 67, drawn to a method for inhibiting an antigen-specific immune response in a subject wherein the antigen-specific response is other than an allergic condition or asthma

Art Unit: 1644

comprising administering to a subject an antigen and an isolated polymer that includes repeating units of charge motif characteristic of B. fragilis polysaccharide A (PSA), classified in Class 424, subclasses 282.1 and 234.1.

XVIII. Claim 72-73 and 93, drawn to a composition comprising a conjugate comprising an antigen and a polymer having repeating units of charge motif characteristic of B. fragilis polysaccharide A (PSA), an aerosol formulation of the polymer and an aerosol delivery system, classified in Class 424, subclasses 234.1, 282.1 and 184.1.

4. Groups I-XVIII are different methods. The recited methods differ with respect to ingredients, method steps, and endpoints; therefore, each method is patentably distinct.

5. Groups XVIII and I-XVII are related as product and process of using. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polymer of Group XVIII can be used for generation of monoclonal antibodies, in addition to the methods recited.

6. These inventions are distinct for the reasons given above. In addition, they have acquired a separate status in the art as shown by different classification and/or recognized divergent subject matter. Further, even though in some cases the classification is shared, a different field of search would be required based upon the structurally distinct products recited and the various methods of use comprising distinct method steps. Therefore restriction for examination purposes as indicated is proper. Further, a prior art search also requires a literature search. It is an undue burden for the examiner to search more than one invention.

Species Election

7. Irrespective of whichever group applicant may elect, applicant is further required under 35 U.S.C. 121: (1) to elect a single disclosed species to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

A. If any one of Groups I-VIII is elected, applicant is required to elect a single disclosed polymer species with a specified structure including a specified negatively charged moiety selected from carboxyl, phosphate, phosphonate, sulfate and sulfonate. Further, applicant is required to elect a single anti-allergy medicament as set forth in claim 17.

These species are distinct because the methods differ with respect to ingredients, pathological conditions and therapeutic endpoints; thus each condition represents patentably distinct subject matter.

B. If Group IX is elected, applicant is required to elect a single disclosed polymer species with a specified structure including a specified negatively charged moiety selected from carboxyl, phosphate, phosphonate, sulfate and sulfonate and a specified n integer species. Further, applicant is required to elect a single anti-allergy medicament as set forth in claim 17.

These species are distinct because the methods differ with respect to ingredients, pathological conditions and therapeutic endpoints; thus each condition represents patentably distinct subject matter.

C. If Group X is elected, applicant is required to elect a single disclosed polymer species with a specified structure including a specified negatively charged moiety selected from carboxyl, phosphate, phosphonate, sulfate and sulfonate; a specified Xaa sequence; a specified m integer; and a specified n integer species. Further, applicant is required to elect a single anti-allergy medicament as set forth in claim 17.

These species are distinct because the methods differ with respect to ingredients, pathological conditions and therapeutic endpoints; thus each condition represents patentably distinct subject matter.

D. If any one of Groups XI-XVIII is elected, applicant is required to elect a single disclosed polymer species with a specified structure as recited in Claims 1-16 with a specified negatively charged moiety selected from carboxyl, phosphate, phosphonate, sulfate and sulfonate.

These species are distinct because the methods differ with respect to ingredients, pathological conditions and therapeutic endpoints; thus each condition represents patentably distinct subject matter.

E. If Group XVI is elected, applicant is required to elect a single population of T cells.

These species are distinct because the methods differ with respect to ingredients, pathological conditions and therapeutic endpoints; thus each condition represents patentably distinct subject matter.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

8. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

9. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

10. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

11. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

Art Unit: 1644

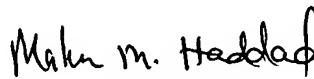
application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nora M. Rooney whose telephone number is (571) 272-9937. The examiner can normally be reached Monday through Friday from 8:30 am to 5:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

December 11, 2006

Nora M. Rooney, M.S., J.D.
Patent Examiner
Technology Center 1600


MAHER M. HADDAD
PRIMARY EXAMINER